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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,595	06/20/2006	Eric Francis Morand	11982.105003(BDW004)	2505
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1180 PEACHTREE STREET, NE				
ATLANTA, GA 30309-3521				
EXAMINER				
CHU, YONG LIANG				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
12/30/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/552,595

**Applicant(s)**

MORAND ET AL.

**Examiner**

YONG CHU

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/28/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 47-57 is/are pending in the application.
- 4a) Of the above claim(s) 50, 54 and 57 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 55 is/are allowed.
- 6) ☒ Claim(s) 47-49, 51-53 and 56 is/are rejected.
- 7) ☒ Claim(s) 47-49, 51-53 and 56 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission on 10/28/2009 has been entered. Upon entering the submission, claims 47-57 are currently pending in the instant application.

### ***Response to RCE Submission***

#### **Claim rejection under 35 U.S.C. §112, 1<sup>st</sup> paragraph, written description**

Applicants' amendment by deleting the rejected term "prodrug" has obviated the rejection.

#### **Claim rejection under 35 U.S.C. §102(b)**

Applicants' amendment by deleting that ~~–N(R5)–~~ is "selected from ~~–N(H)–~~" has obviated the rejection.

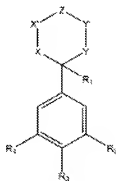
#### **Claim rejection under 35 U.S.C. §103(a)**

Applicants argument regarding the 103(a) rejection on the ground that the previously cited '079 compound in Example 53 is a starting material not a pharmaceutical compound has been fully considered and is found persuasive. The '079 compound does not share the core structure of the '079 invention, and has no pharmaceutical activity even though it is included in the Examples of invention of the specification. Therefore, the rejection is withdrawn.

Since all the rejections have been overcome, search and examination are expanded to partial non-elected subject matter of the scope as follows:

**Provisionally Elected and Examined Subject Matter**

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



A compound of formula (I) according to claim 47, wherein

Z forms a covalent single bond between X' and Y';

X and X' taken together form -CH=N-, and X is -CH-, and X' is N;

Y' is -N(C<sub>2-20</sub>alkyl)-; and Y is -CH- and taken together with the carbon atom bearing the phenyl ring forms a double bond;

R<sub>1</sub> is absent;

R<sub>2</sub> and R<sub>4</sub> are independently -H, or C<sub>1-3</sub>alkyl; and

R<sub>3</sub> is C<sub>1-3</sub>alkyl or C(R<sub>17</sub>)<sub>3</sub>, wherein R<sub>17</sub> is halogen, or a pharmaceutical composition comprising a compound thereof.

The term "alkyl" is interpreted as an optionally substituted alkyl in light of the definition at paragraphs [0094-0095] of the instant specification.

As a result of the election and the corresponding scope of the invention identified supra, claim 50, 54, 57, and the remaining subject matter of claims 47-49, 51-53, and

56 are further withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups, which are chemically recognized to differ in structure, function, and reactivity. Claim 57 is pharmaceutical composition according to claim 56 further comprising a glucocorticoid, which is patentably distinct from the instantly examined claims, and may be rejoined if the instantly examined compound claims are allowable. Therefore, claims 47-49, 51-53, 55 and 56 are examined on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-49, 51-53 and 56 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, substituent **A** is not defined in claim 47. Because of depending on claim 47, claims 49, 51-53, 55, and 56 are rejected accordingly.

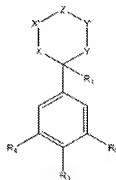
***Claim Rejections - 35 USC § 102(b)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47, 49, 51 and 56 are rejected under 35 U.S.C. 102 (b) as being anticipated by Barrett et al., *PCT publication WO2003-013518* ("the '518 publication").



Applicants' claims relate to a compound of formula (I) according to claim 47, wherein

**Z** forms a covalent single bond between **X'** and **Y'**;

**X** and **X'** taken together form  $-\text{CH}=\text{N}-$ , and **X** is  $-\text{CH}-$ , and **X'** is **N**;

**Y'** is  $-\text{N}(\text{C}_{2-20}\text{alkyl})-$ ; and **Y** is  $-\text{CH}-$  and taken together with the carbon atom bearing the phenyl ring forms a double bond;

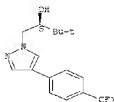
**R<sub>1</sub>** is absent;

**R<sub>2</sub>** and **R<sub>4</sub>** are independently  $-\text{H}$ , or  $\text{C}_{1-3}\text{alkyl}$ ; and

**R<sub>3</sub>** is  $\text{C}_{1-3}\text{alkyl}$  or  $\text{C}(\text{R}_{17})_3$ , wherein **R<sub>17</sub>** is halogen, or a pharmaceutical composition comprising a compound thereof.

The term "alkyl" is interpreted as an optionally substituted alkyl in light of the definition at paragraphs [0094-0095] of the instant specification.

The '518 publication (published on 02/20/2003) disclose the compound (CAS RN



497946-99-3) as an intermediate, This compound is disclosed in example 1f on page 44 of the specification, which reads on the instantly claimed scope of invention wherein **Z** forms a covalent single bond between **X'** and **Y'**; **X** and **X'** taken together form  $\text{-CH=N-}$ , and **X** is  $\text{-CH-}$ , and **X'** is **N**; **Y'** is  $\text{-N(C}_{2-20}\text{alkyl)-}$ , wherein alkyl is substituted by  $\text{-OH}$ ; and **Y** is  $\text{-CH-}$  and taken together with the carbon atom bearing the phenyl ring forms a double bond; **R**<sub>1</sub> is absent; **R**<sub>2</sub> and **R**<sub>4</sub> are independently  $\text{-H}$ , or  $\text{C}_{1-3}\text{alkyl}$ ; and **R**<sub>3</sub> is  $\text{C}_{1-3}\text{alkyl}$  or  $\text{C(R}_{17}\text{)}_3$ , wherein **R**<sub>17</sub> is halogen. Therefore, the '518 compound anticipates the instantly examined scope.

***Claim Rejections - 35 USC § 103(a)***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

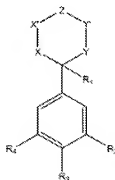
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 47, 49, 51 and 56 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Barrett et al., the '518 publication.



Applicants' claims relate to a compound of formula (I) according to claim 47, wherein

**Z** forms a covalent single bond between **X'** and **Y'**;

**X** and **X'** taken together form  $\text{--CH=N--}$ , and **X** is  $\text{--CH--}$ , and **X'** is N;

**Y'** is  $\text{--N(C}_{2-20}\text{alkyl)--}$ ; and **Y** is  $\text{--CH--}$  and taken together with the carbon atom bearing the phenyl ring forms a double bond;

**R**<sub>1</sub> is absent;

**R**<sub>2</sub> and **R**<sub>4</sub> are independently  $\text{--H}$ , or  $\text{C}_{1-3}\text{alkyl}$ ; and

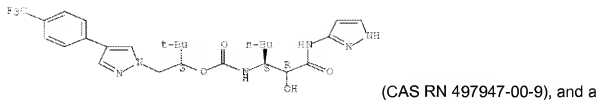
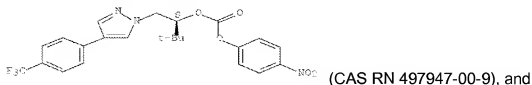
**R**<sub>3</sub> is  $\text{C}_{1-3}\text{alkyl}$  or  $\text{C(R}_{17}\text{)}_3$ , wherein **R**<sub>17</sub> is halogen, or a pharmaceutical composition comprising a compound thereof.

The term "alkyl" is interpreted as an optionally substituted alkyl in light of the definition at paragraphs [0094-0095] of the instant specification.

Determination of the scope and content of the prior art (MPEP §2141.01)



The '518 publication discloses specific pharmaceutical compounds



pharmaceutical composition comprising the compound thereof.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the '518 compounds and the instantly claimed invention is  $Y'$  as  $-N(R_5)-$ , wherein  $R_5$  is optionally substituted  $C_{2-20}$ alkyl for the instant application, while  $R_5$  is an alkyl substituted by a polar phenyl carbonate group or a polar carbamate group.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

However, the instantly claimed invention would have been obvious over the '518 publication, because compounds share the same core structure, and differ only in the non-specific substituents. In addition, the  $R_5$  substituents in the '518 publication are polar substituents, which is preferred by the instant application. The motivation to make the claimed compounds derives from the expectation that structurally closely related compounds share the similar pharmaceutical property.

### ***Claim Objections***

Claims 47-49, 51-53 and 56 are provisionally objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra.

### ***Conclusion***

- Claim 55 is allowed.
- Claims 47-49, 51-53 and 56 are rejected.
- Claims 47-49, 51-53 and 56 are objected to.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu, Ph.D., whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu/  
Primary Patent Examiner  
Art Unit 1626